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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,827	10/23/2001	John Jacob Schwartz	ENZ-004	6161
28120	7590	07/01/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,827

Applicant(s)

SCHWARTZ ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 12-20, 25-33, and 36-54, drawn to engineered chimeric protein comprising ligand binding domain, sensor cell, genetic switch, logic gate, and cellular system, classified in class 530, subclasses 300 and 350 and class 435, subclass 325.
- II. Claims 4-17, 21-33, and 36-66, drawn to engineered chimeric protein comprising a detection domain, sensor cell, genetic switch, logic gate, and logic system, classified in class 530, subclasses 300 and 350 and class 435, subclass 325.
- III. Claims 34-35, only as drawn to nucleic acid and vector encoding chimeric protein comprising ligand binding domain, classified in class 536, subclass 23.1 and class 435, subclass 320.1.
- IV. Claims 34-35, only as drawn to nucleic acid and vector encoding chimeric protein comprising detection domain, classified in class 536, subclass 23.1 and class 435, subclass 320.1.

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- V. Claims 67-71 and 73-76, drawn to method of engineering a ligand-responsive chimeric protein, classified in class 435, subclass 91.4.
- VI. Claims 72-76, drawn to method of engineering a stimulus-responsive chimeric protein, classified in class 435, subclass 91.4.
- VII. Claim 79, drawn to method of engineering a stimulus-responsive chimeric protein using a database, classified in class 435, subclass 91.4.
- VIII. Claim 79, drawn to method of engineering a stimulus-responsive chimeric protein using a library, classified in class 435, subclass 91.4.
- IX. Claims 81-83, only as drawn to method of detecting a molecule in solution using a sensor cell comprising an engineered chimeric protein comprising ligand binding domain, classified in class 435, subclass 29.
- X. Claims 81-83, only as drawn to method of detecting a molecule in solution using a sensor cell comprising an engineered chimeric protein comprising detection domain, classified in class 435, subclass 29.
- XI. Claim 84, only as drawn to method of detecting a disease using a sensor cell comprising an engineered

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chimeric protein comprising ligand binding domain,
classified in class 800, subclass 3.

XII. Claim 84, only as drawn to method of detecting a
disease using a sensor cell comprising an engineered
chimeric protein comprising detection domain,
classified in class 800, subclass 3.

XIII. Claim 85, only as drawn to method of detecting a
disease marker using a sensor cell comprising an
engineered chimeric protein comprising ligand binding
domain, classified in class 435, subclass 29.

XIV. Claim 85, only as drawn to method of detecting a
disease marker using a sensor cell comprising an
engineered chimeric protein comprising detection
domain, classified in class 435, subclass 29.

XV. Claims 86-90, only as drawn to method of treating a
patient using a sensor cell comprising an engineered
chimeric protein comprising ligand binding domain,
classified in class 424, subclass 93.2.

XVI. Claims 86-90, only as drawn to method of treating a
patient using a sensor cell comprising an engineered
chimeric protein comprising detection domain,
classified in class 424, subclass 93.2.

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XVII.Claim 91, only as drawn to method of monitoring a fermentation process using a sensor cell comprising an engineered chimeric protein comprising ligand binding domain, classified in class 435, subclass 29.

XVIII.Claim 91, only as drawn to method of monitoring a fermentation process using a sensor cell comprising an engineered chimeric protein comprising detection domain, classified in class 435, subclass 29.

XIX. Claim 92, only as drawn to method of screening drug candidates using a sensor cell comprising an engineered chimeric protein comprising ligand binding domain, classified in class 435, subclass 29.

XX. Claim 92, only as drawn to method of screening drug candidates using a sensor cell comprising an engineered chimeric protein comprising detection domain, classified in class 435, subclass 29.

XXI. Claim 93, only as drawn to method of identifying a nucleic acid using a sensor cell comprising an engineered chimeric protein comprising ligand binding domain, classified in class 435, subclass 6.

XXII.Claim 93, only as drawn to method of identifying a nucleic acid using a sensor cell comprising an

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engineered chimeric protein comprising detection domain, classified in class 435, subclass 6.

XXIII. Claims 94-95, only as drawn to method of positioning a cell using a sensor cell comprising an engineered chimeric protein comprising ligand binding domain, classified in class 435, subclass 375.

XXIV. Claims 94-95, only as drawn to method of positioning a cell using a sensor cell comprising an engineered chimeric protein comprising detection domain, classified in class 435, subclass 375.

XXV. Claims 96-97, only as drawn to method of patterned molecular synthesis using a sensor cell comprising an engineered chimeric protein comprising ligand binding domain, classified in class 435, subclass 375.

XXVI. Claims 96-97, only as drawn to method of patterned molecular synthesis using a sensor cell comprising an engineered chimeric protein comprising detection domain, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups I-IV are chemically, biologically, and functionally distinct from each other and thus one does not

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render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups V-XXVI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups V-XXVI comprise steps which are not required for or present in the methods of the other groups. The end result of the methods are different from each other. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups V and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

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In the instant case the product as claimed can be made by a materially different process, such as by modeling.

Inventions of Groups VI-VIII and Group II are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process, as evidenced by the distinct inventions of Groups VI-VIII.

Inventions of Group I and Groups IX, XI, XIII, XV, XVII, XIX, XXI, XXIII, and XV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, as evidenced by the distinct inventions of Groups IX, XI, XIII, XV, XVII, XIX, XXI, XXIII, and XV.

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Inventions of Group II and Groups X, XII, XIV, XVI, XVIII, XX, XXII, XXIV, and XVI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, as evidenced by the distinct inventions of Groups X, XII, XIV, XVI, XVIII, XX, XXII, XXIV, and XVI.

Except for the specific relationships described above, the inventions of Groups I-IV are unrelated to Groups V-XXVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I-IV are not used in or made by the methods of Groups V-XXVI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not required for the other groups because each group

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requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species (types) of the claimed invention:

1. target biomolecule
2. interaction domain
3. effect detectable outside of sensor cell
4. stimulus
5. biological gate type
6. change in response to expression of reporter gene
7. first stimulus/second stimulus/second stimulus response
8. peptide identifying step
9. permissive position identified
10. abnormal state

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each type (applicable to the elected invention) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be

allowable. Currently, claims 1-97 are generic for one or more species types.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined

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process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the

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scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 28, 2004